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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,883	03/26/2001	Jorg Peter Schur	VONKREISLER.	8618
110 7590 03/28/2008 DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			EXAMINER YOUNG, MICAH PAUL	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 03/28/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/743,883	Applicant(s) SCHUR, JORG PETER	
	Examiner MICAH-PAUL YOUNG	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46,57,58,61 and 63-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46,57,58,61 and 63-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/11/08 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 46,57,58,61,63,64 and 66-70 rejected under 35 U.S.C. 103(a) as being unpatentable over the combine disclosures of Honda (USPN 5,750,563 hereafter '563) in view of Hughes et al (USPN 5,322,689 hereafter '689) and Carson et al (USPN 5,416,075 hereafter '075). The claims are drawn to a composition comprising a polyphenols along with lactic acid.

5. The '563 patent is drawn to a preparation comprising polyphenols, antimicrobial agents and carrier materials (abstract, col. 4, lin. 20-25). The composition comprises at least one gallic acid derivatives such as tannic acid, a flavonoid such as gossypetin and various extracts and

Art Unit: 1618

essential oils such as camphor (col. 3, lin. 25-col. 4, lin. 26, claim 1). The components of the composition are present in concentrations from 0.1 to 20 % (*Ibid.*). The reference is silent to the inclusion of lactic acid yet suggest the inclusion of humectants. Lactic acid is well known humectant as seen by the '689 patent.

6. The '689 patent discloses a topical aromatic formulation comprising antibiotics, and carriers (col. 7, lin. 3-68). These carriers are present in a concentration from 1-10% (col. 7, lin. 40-45). The carriers include humecatanant/moisterizers like lactic acid, extracts such as camphor and eucalyptus oil and phenols such as thymol (examples).

7. Regarding the concentration of the components it is the position of the Examiner that the general conditions of the claims have been met. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

8. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

9. Regarding claims 63 and 66 it is the position of the Examiner that any composition without an antimicrobial component is susceptible to infection. This would extend to the carrier formulation for the '563 reference. Without the antimicrobial component the carrier composition

Art Unit: 1618

would be susceptible to infection. It is the position of the Examiner that the '563 reference is inherently a formulation microbially perishable product containing the antimicrobial composition of the invention.

10. Regarding claim 65, as discussed above the '563 patent discloses an antimicrobial composition comprising polyphenols, and other active agents. The patent suggests the inclusion of extracts of an animal or vegetable origin but is silent to the specific extracts recited by the claims. However tea extracts (*Camellia sinensis*) have long been known for their antimicrobial properties. These properties are discussed in the '075 patents.

11. The '075 patent discloses antimicrobial emulsions comprising extracts and antimicrobial compounds (abstract). The extracts include essential oils including camphor orange oil and anise oil (col. 8, lin. 38-53). A skilled artisan would have been able to follow the suggestions '563 to include vegetable and essential oils, and include the anise oil of '075 in order to add flavor and an aromatic effect.

12. With these things in mind it would have been obvious to a skilled artisan to follow the teachings and suggestions of the reference in order to provide an optimized antimicrobial formulation. The artisan of ordinary skill would have been motivated to include the humectants of the '689 patent into the formulation of the '563 in order to improve the stability of the formulation. A skilled artisan would have been motivated to include the extracts of the '075 into the formulation of '563 in order to improve the antimicrobial fighting effects and improve the flavor and aromatic properties of the composition. These combinations would have been made under the suggestion of '563 to include essential oils and plant/vegetable extracts into the formulation. It would have been obvious to one of ordinary skill in the art to follow these

Art Unit: 1618

suggestions and teachings with an expected result of an antimicrobial formulation useful in treating infections and preserving products.

Response to Arguments

13. Applicant's arguments filed 1/11/08 have been fully considered but they are not persuasive. Applicant argues that;

a. Since the kojic acid required by the '563 patent is not GRAS, it changes the fundamental properties of the composition and, therefor does not obviate the claims.

b. None of the patents teach or obviate the instant invention since they do not disclose an antimicrobial formulation comprising a polyphenols and no other flavoring alcohols.

14. Regarding argument a., although kojic acid is not GRAS that does not preclude it from being included into the formulation. The instant invention is *not* GRAS; it merely cannot comprise any other GRAS compounds. That does not make the *entire* composition GRAS. The instant invention is recited to antimicrobial, and it achieved this property by the presence of the polyphenols compounds in preferred concentrations. The '563 patent provides compositions comprising tannic acid derivatives (claim 1). These compounds are present in an amount from 01-20% within the limits of the instant claims and sufficient to provide an antimicrobial effect. Applicant argues that kojic acid is GRAS; however the compound is used in food preservation such as seafood to preserve the pink color or to stop the discoloration of cut fruit. As such the compound is safe for human consumption and would be useful in perishable products such as those recited in claim 66. This compound would not change the fundamental properties of the

Art Unit: 1618

composition and therefor the '563 composition in combination with the '689 patent would continue to obviate the claims.

15. Regarding argument b., it remains the position of the Examiner that the combination of the '563 and '689 patent would provide an obviating composition, that meets all of the limitations of the instant claims. The '563 patent discloses a composition comprising kojic acid and tannic acid derivative, along with optional humectant and emollients. These emollients are well known in the art and can be seen in the '689 patent. The '689 patent provides a composition comprising antibiotics and carriers such as lactic acid (col. 7, lin. 3-68). Benzyl alcohol is only listed in the alternative and is not a required component. The patent establishes the level of skill in the art regarding lactic acid and its use as a carrier compound. Also the lactic acid is present in a concentration within the limits of the instant claims. It would have been obvious to include the lactic acid compounds of the '689 patent into the preservative compound of the '563 patent in order to provide a stable formulation. For these reasons the claims remain obviated.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Micah-Paul Young
Examiner
Art Unit 1618

/Micah-Paul Young/
Examiner, Art Unit 1618